

## REMARKS

### Rejections Under 35 U.S.C. §§102 and 103

The rejection of claims 23-24 under 35 U.S.C. §103 in view of Belleau et al. (US 5,047,407) is traversed for the reasons of record. See, e.g., the arguments presented at pages 11-19 of the Response filed October 16, 1997.

Similarly, the rejection of claims 23-24 under 35 U.S.C. §§ 102 and 103 in view of Liotta et al. (US 5,539,116) is traversed for the reasons of record. Again, see, e.g., the Response filed October 16, 1997.

At page 3 of the Office Action it is stated that claim 7 is obvious under 35 U.S.C. §103. However, the references relied on for this rejection are not clearly identified. Presumably, the rejection is based on either US '407 or US '116 taken in combination with Remington's Practice of Pharmacy. This rejection is traversed for the reasons of record traversing the rejections based on US '407 and US '116 alone.

Throughout the Office Action of January 7, 1998, numerous references are made to the reported decision *Emory University v. Glaxo Wellcome Inc.*, 44 USPQ2d 1407 (N.D. Ga, 1997). This decision is quite relevant. It demonstrates that the District Court is presently dealing with the same issues raised in the rejections made by the Examiner.

In the rejection in view of the '116 patent, the Examiner argues that Liotta et al. contend that the '116 patent shows possession of the (-) enantiomer. To support this point, the Examiner refers to the District Court's mention of the Klivanov declaration at 44 USPQ2d 1413. While the District Court did acknowledge this contention by Emory, it did not hold that US '116 actually showed possession of the (-) enantiomer. The issue before the Court was a Summary Judgment Motion, including whether there was a material fact in dispute as to the '116 patent satisfying the written description requirement under 35 U.S.C. §112, 1<sup>st</sup> paragraph.

The District Court did not decide that the '116 patent met the written description requirement. Instead, the Court denied Glaxo's motion for Summary Judgment that the '116 patent was invalid by finding that material facts were in dispute. In particular, the District Court held "that genuine issues of material fact remain on the question of whether the specification of

the '116 patent contains an adequate written description of the claimed invention 3TC." See 44 USPQ2d at 1414.

In the rejection in view of US'407, it is argued that the racemate renders obvious the individual enantiomers. The District Court addressed this same issue when it considered Glaxo's Motion for Summary Judgment on grounds that the '116 patent was invalid as being obvious in view of '407.

The Court held that a racemate renders the separate enantiomers *prima facie obvious*. But, the Court did not consider this to be an absolute bar to patentability. As a result the Court held that it could not "at this time, legally conclude that the subject matter of Emory's '116 patent was obvious over BioChem's prior disclosure of BCH-189."

Thus, it is evident that the issues raised by the Examiner were considered by the District Court in the Northern District of Georgia. However, the Court did not make a final determination. Thus, the issues are still part of the ongoing litigation between Glaxo and Emory.

#### **Request for Suspension of Prosecution**

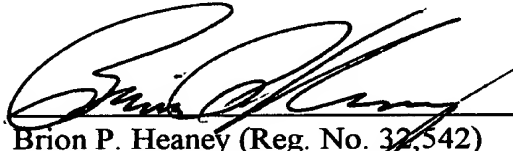
In addition to the District Court case discussed above, the dispute surrounding 3TC and the rights thereto in conjunction with the disclosures of US'407 and US'116 is now before a tribunal of the PTO. As the Examiner is well aware, an interference has been initiated between BioChem's patent application Serial No. 08/468,362 and Emory's '116 patent. Application Serial No. 08/468,362 was prosecuted before the present Examiner. This application has been awarded priority in the pending interference (No. 104,201) based on the disclosure in Serial No.308,101, i.e., the application which issued as US'407.

Issues raised in the case before the Court in Georgia and the issues raised by the Examiner in this instant application will certainly be brought up in this pending interference. Therefore, it would be appropriate to suspend proceedings in the instant application pending the outcome of the interference and the litigation.

Since the review tribunal of the Patent and Trademark Office will address the issues raised by the Examiner, it would be wasteful and futile to continue *ex parte* prosecution of the instant application until the interference is resolved. Therefore, since the issues raised by the Examiner

will be addressed by PTO in the pending interference, applicants' respectfully request that prosecution of the instant application be suspended for at least six months.

Respectfully submitted,



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